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SENATE BILL 132 By
Jackson

HOUSE BILL 254
By Shepard

AN ACT to amend Tennessee Code Annotated, Title 56; Title 63
and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. This act may be cited as the "Tennessee Senior Citizen Prescription Drug Discount Card Program Act of 2003".

SECTION 2. The general assembly finds that:

- (1) Although senior citizens represent twelve percent (12%) of the population, they use on average thirty-seven percent (37%) of prescription drugs that are dispensed.
- (2) Senior citizens in the United States without prescription drug insurance coverage pay the highest prices in the world for needed medications.
- (3) High prescription drug prices force many Tennessee seniors to go without proper medication or other necessities, thereby affecting their health and safety.

(4) Prescription drug prices in the United States are the world's highest, averaging thirty-two percent (32%) higher than in Canada, forty percent (40%) higher than in Mexico, and sixty percent (60%) higher than in Great Britain.

(5) Prescription drug prices listed on the federal supply schedule that serve the veterans' administration, the department of defense, and the coast guard average fifty-two percent (52%) below the non-federal average manufacturer's price.

(6) Regardless of household income, seniors without prescription drug coverage are often just one serious illness away from poverty.

(7) Reducing the price of prescription drugs would benefit the health and well-being of all Tennessee senior citizens by providing more affordable access to needed drugs.

(8) Drug prices on the federal supply schedule are negotiated by the department of veterans' affairs and are the best publicly available indicator of the prices that drug companies charge their favored customers.

SECTION 3. The purpose of this program is to require the department of health to establish and administer a program that will enable eligible senior citizens to purchase prescription drugs at discounted prices.

SECTION 4. As used in this act:

(1) "Commissioner" means the commissioner of health, or the commissioner's designee or designees.

(2) "Department" means the department of health.

(3) "Drug manufacturer" means any entity located within or outside Tennessee that is engaged in (i) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products covered under the program, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical

synthesis or (ii) the packaging, repackaging, leveling, labeling, or distribution of prescription drug products covered under the program. "Drug manufacturer," however, does not include a wholesale distributor of drugs or a retail pharmacy licensed under Tennessee law.

(4) "Eligible senior" means a person who is (i) a resident of Tennessee, (ii) sixty-five years of age or older, (iii) has household income at or below the three hundred percent (300%) of the federal poverty level, and (iv) has no private or public insurance coverage for prescription drugs.

(5) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the federal food and drug administration under 21 Code of Federal Regulations, Section 207.20.

(6) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(7) "Participating Retail Pharmacy" means a retail pharmacy or other business licensed to dispense prescription drugs in this state that:

(A) participates in the state medical assistance program, or

(B) voluntarily agrees to participate in the program.

(8) "Prescription drug" means any prescribed drug that may be legally dispensed by an authorized pharmacy.

(9) "Program" means the senior citizen prescription drug discount program created under this act.

(10) "Rules" includes rules promulgated and forms prescribed by the department.

SECTION 5. The senior citizen prescription drug discount program is established to protect the health and safety of senior citizens. The program shall be administered by the

department. The program is established within the department to lower prescription drug prices for uninsured and underinsured residents of the state. The department shall (i) enroll eligible seniors into the program to qualify them for a discount on the purchase of prescription drugs at a participating retail pharmacy, (ii) enter into rebate agreements with drug manufacturers, and (iii) reimburse pharmacies for the cost of providing discounts using the proceeds from the manufacturer rebate agreements.

SECTION 6.

(a) A drug manufacturer or labeler that sells prescription drugs in the state may voluntarily elect to enter into a rebate agreement with the department.

(b) The commissioner shall negotiate the terms of the rebate from a drug manufacturer or labeler, taking into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts.

(c) If the commissioner and a drug manufacturer or labeler fail to reach agreement on the terms of a rebate, the commissioner shall prompt a review of whether to place such manufacturer's or labeler's products on the prior authorization list for the state medical assistance program pursuant to Tennessee Code Annotated, Section 71-5-108, and take similar actions involving prior authorization or formularies for any other state-funded prescription drug program. The commissioner shall promulgate rules creating clear procedures for the implementation of this subdivision. The names of manufacturers and labelers that do not enter into rebate agreements are public information, and the department shall release this information to the public. The commissioner shall

also publicize to doctors, pharmacists, and other health professionals information about the relative cost of drugs produced by manufacturers and labelers that enter into rebate agreements compared to those who do not enter into rebate agreements.

(d) A participating retail pharmacy shall discount the price of prescription drugs sold to program participants.

(1) The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.

(2) Beginning July 1, 2003, a participating retail pharmacy shall offer prescription drugs at or below the average wholesale price, minus six percent (6%), plus a dispensing fee designated by the commissioner. These initial price levels shall be calculated by the commissioner, and the dispensing fee shall not be less than that provided under the state medical assistance program. The average wholesale price is the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug-pricing file.

(3) No later than January 1, 2004, a participating retail pharmacy shall offer prescription drugs at or below the initial price levels specified in subdivision (2) minus the amount of any rebate paid by the state to the retail pharmacy. These discounted price levels shall be calculated by the commissioner. In determining the discounted price levels, the commissioner shall consider an average of all rebates weighted by sales

of drugs subject to these rebates over the most recent twelve-month period for which the information is available.

(e)

(1) The board of pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to program participants of the amount of savings provided as a result of the program. The rules must protect information that is proprietary in nature.

(2) The department may not impose transaction charges on participating retail pharmacies that submit claims or receive payments under the program.

(3) A participating retail pharmacy shall submit claims to the department to verify the amount charged to program participants.

(4) On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for discounted prices provided to program participants and dispensing fees set by the commissioner.

(5) The department shall collect from the participating retail pharmacies utilization data necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule, or regulation.

(f) Discrepancies in rebate amounts must be resolved using the process established in this subdivision.

(1) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy

still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

(2) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

(3) Following the procedures established in paragraph (A) or (B), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.

SECTION 7.

(a) Subject to the requirements of Tennessee Code Annotated, Title 12, Chapter 4, Part 7, the department shall compensate participating retail pharmacies from the senior citizen prescription drug discount program fund for the difference between the amount paid by eligible seniors for prescription drugs dispensed under the program and the AWP minus ten percent (10%).

(b) All rebates negotiated under agreements described in this act shall be paid to the department in accordance with procedures prescribed by the department. All rebates must be remitted to the department not later than thirty (30) days after receipt of a request for payment by the department.

(c) The receipts from the rebates and monies transferred under section 8 shall be deposited into the senior citizen prescription drug discount program fund, a special fund hereby created in the state treasury, and shall be used, subject to appropriation, to cover the cost of reimbursing authorized pharmacies pursuant to this act.

SECTION 8.

(a) Within thirty (30) days after the effective date of this act, the state comptroller shall direct and the state treasurer shall transfer such funds as the General Appropriations Act shall specify from the general fund to the senior citizen prescription drug discount program fund to facilitate the payment of reimbursements to authorized pharmacies.

(b) The senior citizen prescription drug discount program fund, referred to in this section as the "fund", is established to receive revenue from manufacturers and labelers who pay rebates and any appropriations or allocations designated for the fund. The purposes of the fund are to reimburse retail pharmacies for discounted prices provided to senior citizen prescription drug discount program participants and to reimburse the department for the costs of administering the program, including contracted services, computer costs, professional fees paid to participating retail pharmacies, and other reasonable program costs. Monies from the fund may be expended to fund activities authorized by this part. Any revenues deposited in this reserve shall remain in the reserve until expended for purposes consistent with this part, and shall not revert to the general fund on any June 30. Any excess revenues on interest earned by such revenues shall not revert on any June 30, but shall remain available for appropriation in subsequent fiscal years. Surplus funds in the fund may be used only for the benefit of the senior citizen prescription drug discount program.

SECTION 9. Any person may apply to the department for participation in the program in the form and manner required by the department. The department shall determine the eligibility

of each applicant for the program within thirty (30) days after the date of application. An eligible senior whose application has been approved by the department shall receive a program identification card. The card may be presented to an authorized pharmacy to assist the pharmacy in verifying eligibility under the program.

SECTION 10.

(a) The department shall promulgate rules to establish standards and procedures for participation in the program and approve those pharmacies that apply to participate and meet the requirements for participation. The department may remove the authorization of a pharmacy to participate in this program for failure to meet the standards and procedures for participation established by the department by rule. Any pharmacy that has been removed as a participating retail pharmacy by the department may apply for reinstatement as a participating retail pharmacy in accordance with standards and procedures established by the department by rule.

(b) The department shall annually review the eligibility of pharmacies to participate in the program.

(c) The department shall establish procedures for properly contracting for pharmacy services, validating reimbursement claims, validating compliance of authorized pharmacies with the conditions for participation required under this act, and otherwise providing for the effective administration of this act. The commissioner, in consultation with pharmacists licensed under Tennessee Code Annotated, Title 63, Chapter 10, may enter into a written contract with any other state agency, instrumentality, or political subdivision or with a fiscal intermediary for the purpose of making payments to participating pharmacies pursuant to section 6 and coordinating the program with other programs that provide payments for prescription drugs covered under the program.

SECTION 11. The department shall promulgate rules to implement and administer the program, which shall include, but not be limited to, the following:

(1) Execution of contracts with pharmacies to participate in the program. The contracts shall stipulate terms and conditions for the participation of authorized pharmacies and the rights of the state to terminate participation for breach of the contract or for violation of this act or rules promulgated by the department under this act.

(2) Establishment of maximum limits on the size of prescriptions that are eligible for a discount under the program, up to a ninety (90) day supply, except as may be necessary for utilization control reasons.

(3) Establishment of liens upon any and all causes of action that accrue to a beneficiary as a result of injuries for which prescription drugs covered under the program are directly or indirectly required and for which the commissioner made payment or became liable for under this act.

(4) Inspection of appropriate records and audits of participating authorized pharmacies to ensure contract compliance and to determine any fraudulent transactions or practices under this act.

SECTION 12. The department shall report to the governor and the general assembly by March 1 of each year on the administration of the program under this act.

SECTION 13. The commissioner is authorized to promulgate rules and regulations to effectuate the purposes of this act. All such rules and regulations shall be promulgated in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 14. The provisions of this act shall not be construed to be an appropriation of funds, and no funds shall be obligated or expended pursuant to this act unless such funds are specifically appropriated by the General Appropriations Act.

SECTION 15. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the

act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 16. For rule making purposes, this act shall take effect on becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2003, the public welfare requiring it.